Updating the Default Input Values for Exposure Variables in the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK Model): *Estimation of Lead Exposure from Water Sources for U.S. Children: Water Lead Concentration*

Peer Review Report

Prepared by:

TRW Lead Committee

Date:

May 22, 2014

TABLE OF CONTENTS

LIST OF APPENDICES

EXECUTIVE SUMMARY

The Peer Review Panel (herein referred to as Panel) reviewed a document titled *Updating the Default Input Values for Exposure Variables in the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK Model), Estimation of Lead Exposure from Water Sources for U.S. Children: Water Lead Concentration* (herein referred to as the Update Document) to address 14 charge questions regarding the information contained in the document.

The Update Document presented a summary of the published literature and an analysis of the available data regarding nationally representative water lead concentrations that children in the United States would be exposed to.

This Peer Review Report is intended to provide a summary of the Panel's comments and the TRW Lead Committee's revisions to the Update Document in response to the Panel's recommendations.

The Panel's review resulted in an editorial revision of the Update Document. The Panel's findings are summarized below in Section 2.2 Summary of Findings and Section 3.0 Results. The revised final Update document may be found at http://epa.gov/superfund/lead/trw.htm.

1.0 INTRODUCTION

1.1 Background

The current default value for the *Lead Concentration in Drinking Water* variable in the IEUBK model represents a national central tendency estimate for lead concentration in drinking water (PbW) in the absence of exposures at the site being assessed. This default value was derived from a combination of the PbW data reported by the American Water Works Service Company, Inc. (AWWSC, 1988) and a quantitative analysis performed by Marcus (1989). The AWWSC (1988) performed a survey of the trace element concentrations and characteristics of ▇▇▇ locations throughout the U.S. (U.S. EPA, 1994a).

The purpose of the Update Document was to provide a recommendation for revising the *Lead Concentration in Drinking Water* variable in the IEUBK model using: 1) a more representative methodology for estimating PbW, and 2) currently available PbW data. Updating the IEUBK model default values may be considered appropriate if evidence is sufficient to indicate that a newer, more representative data and methodology for calculating PbW are available that would be more protective for site risk assessment.

The Update Document presents an analysis of the available data regarding PbW for public water sources in the U.S. The principal objectives of the review and data analysis were as were to:

1. Identify published literature potentially relevant to estimating PbW in the U.S., and to select studies that meet predetermined quality considerations.

2. Evaluate data contained in the pertinent national databases to examine whether they are adequate and sufficient to conclude that the current IEUBK model default value for PbW is representative (or not) for residential scenarios at Superfund sites.

3. Consider use of these data, if adequate and sufficient, to recommend a quantitative central tendency estimate for PbW for use in the IEUBK model.

This Peer Review Report was prepared to provide a summary of the Panel's comments and the TRW Lead Committee's revisions to the Update Document in response to the Panel's recommendations.

2.0 PEER REVIEW PROCESS

2.1 Peer Review Charge

The Update Document qualifies as a technical document and is eligible for an independent peer review of the content. U.S. EPA contracted Environmental Management Support, Inc. (EMS) to conduct an independent peer review of the Update

Document. EMS conducted the review of the technical document in accordance with the U.S. EPA's Science Policy Council Peer Review Handbook (U.S. EPA, 2006). Management of the review consisted of the following general activities:

- Identified areas of expertise necessary for a scientifically rigorous review.
- Identified a list of candidate expert peer reviewers.
- Evaluated the expertise of each of the candidate expert peer reviewers.
- Created a short list of candidate expert peer reviewers.
- Determined the interest and availability of the short list of candidate expert peer reviewers.
- Determined for each of the remaining list of candidate peer reviewers any potential conflict of interest or lack of impartiality, or the appearance of any potential conflict of interest or lack of impartiality; excluding candidates with either.
- Finalized a team of three expert peer reviewers.
- Developed charge questions in conjunction with U.S. EPA for the conduct of the peer review.
- Initiated the review.
- Coordinated the peer reviewers to finalize their written reviews.

The peer review was conducted as a letter review. Each reviewer was provided a copy of the Update Document and charge questions.

In seeking candidates to serve as peer reviewers, as well as selecting the final team of reviewers, an effort was made to include individuals with expertise in one of more of the areas identified by U.S. EPA:
- Water Lead Surveys
- Lead Toxicokinetics and Toxicokinetics Modeling
- Exposure Assessment or Risk Assessment
- Toxicology
- Mathematical Modeling
- Environmental Health, Science, or Environmental Engineering

The final team of expert reviewers on the Panel consisted of the following:
- Dr. Serap Erdal, University of Illinois – Chicago School of Public Health;
- Dr. Paul Mushak, PB Associates; and
- Dr. Simoni Triantafyllidou, Virginia Tech.

The TRW Lead Committee thanks the Panel for providing valuable comments on the Update Document.

Efforts were made to ensure that each Panel member was allowed sufficient time to complete their review. Upon receipt by EMS, each letter review was examined and formatted for delivery to U.S. EPA. A brief summary of the Panel's findings is included in Section 3.1. U.S. EPA's charge to the Panel and a summary of the Panel's findings is

included below. A summary of the Panel's comments are included as an appendix to this document.

2.2 Summary of Findings

- Each reviewer agreed that the Update Document needs to be reorganized for clarity and that additional information is needed to support updating the IEUBK model default values. Specifically, the reviewers noted that the document should have the following: 1) additional exploration on lead levels in tap water (vs. at lead levels at the water treatment plant); 2) detail to document the data and methods used; and 3) the impact of these changes in the IEUBK model.

- Two of the three members of the Panel noted that the Update Document would only be acceptable with major revisions.

3.0 RESULTS

The Panel's review comments were reviewed and considered by the TRW Lead Committee and resulted primarily in an editorial revision of the Update Document. The Panel recommended revising the Update Document's organization, but did not alter the scientific methodologies, including the databases used. In addition to the reorganization, text was added to the Update Document to clarify the objective and findings based on the comments received from the Panel. Sections were retitled and reorganized as the following:

Peer Review Draft	Revised Draft
Overview	Overview
Analysis	Technical Analysis
References	Uncertainty
	Recommendations for the IEUBK Model
	Impact on the IEUBK Model Predictions
	References

The Panel provided a combined total of 63 comments. The majority of the comments were directed towards reorganizing the document for clarity. Each comment was reviewed by the TRW Lead Committee and resolutions were incorporated into a revised draft.

Based on the review of the Update Document, two members of the Panel recommended that the update of the *Lead Concentration in Drinking Water* variable in the IEUBK model was: **Acceptable with major revision (as outlined)**. The third Panel member recommended that the update was **Not Acceptable (under any circumstance).**

The Appendix presents a summary of peer review questions and comments. The revised final Update Document may be found at http://epa.gov/superfund/lead/trw.htm.

3.1 Selected Comments

Representative comments were selected to demonstrate the process, changes made in the document in response to the peer review comments, and overall consensus of the peer review. In the text below, black font indicates original text, red font indicates new text, and strikeout indicates deleted text.

COMMENT (1): The draft does contain some of the sections needed for an analysis of default values for children's water Pb consumption rates in the IEUBK model. The draft can be expanded with some added sections, as could some other documents in this suite of analyses, under such headings as "Implications" for the IEUBK model, "Results" or "Analysis and Results", "Limitations of the Methodologies", "Scope of the Methodologies".

COMMENT (2): The document is not yet complete and it is, at best, be described as an early draft. It provides very minimal justification for the proposed value. Although it is concise, it is concise at the expense of being logical and clear. The EPA also has not explained all the literature and data sources adequately.

COMMENT (3): For the benefit of the IEUBK model user, I believe that the IEUBK manual should explain what this water lead input aims to represent (*e.g.*, that it is meant to be a national representative value of constant tap water lead exposure and that it does not account for filter usage or bottled water consumption).

Response to Comments 1, 2 & 3: The Update Document was reorganized for clarity and additional sections and text were added describing how the PbW value was calculated. Specifically, an 'Overview', 'Technical Analysis', 'Uncertainty', 'Recommendations for the IEUBK Model' and 'Impacts on the IEUBK Model Predictions' sections were added.

COMMENT (4): Because technical basis of proposed change is not documented in the text, the first priority should be documenting all data, data analysis methods, results in tables and graphs to demonstrate to the reader and the public that the proposed change is in line with current practice and scientific protocols. Furthermore, a number of statistical metrics for the exposure concentration should be presented.

Comment (5): I am confused about the origin of the dataset used in the TRW analysis, because I could not find any information about lead data in the cited 6-year review report. Aside from access to that dataset, I understood that the majority of those samples do not reflect lead in tap water. To the extent my understanding is correct; I do not believe the dataset is representative of exposure at the tap, as an input to the IEUBK model.

COMMENT (6): For the dataset that is chosen, I believe that a figure similar to Figure 1 is important, because a frequency distribution and a formal statistical analysis of the data can provide useful information.

Response to Comment 4, 5 & 6: The Six-Year Review dataset was provided to the peer reviewers. The text was reviewed and additional technical details were added. Tables and Figure are not shown.

Text Added to the 'Overview':

The current default value for the Lead Concentration in Drinking Water variable in the IEUBK model represents a national central tendency estimate for lead concentration in drinking water (PbW). ~~The TRW Lead Committee evaluated the default lead concentration in drinking water (PbW) variable of the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK model) as part of an effort to review the input variables of the model.~~ This default value ~~(Version 1.1, Build 11) is based on values~~ was derived from a combination of PbW data reported by the American Water Works Service Company, Inc. (~~U.S. EPA, 1994a~~ AWWSC, 1988) and ~~the IEUBK Model Technical Support Document (U.S. EPA, 1994b).~~ a quantitative analysis performed by Marcus (1989).[1] The TRW recommends updating the Lead Concentration in Drinking Water variable with a population-weighted value derived from the U.S. EPA's Second Six-Year Review of National Primary Drinking Water Regulations, or "Six-Year Review" (U.S. EPA, 2010a,b; see Table 1).[2]

The purpose of this document is to review the currently available data on lead in U.S. drinking water, provide the technical basis for updating the Lead Concentration in Drinking Water variable, and to recommend an updated default PbW value for use in the IEUBK model. The intended audience for this document is risk assessors who are familiar with using the IEUBK model. For further background information on the use of the IEUBK model in Superfund lead risk assessment, refer to U.S. EPA (1994a) or the Technical Review Workgroup for Lead (TRW) website (http://epa.gov/superfund/lead/trw.htm).

Text added to the 'Technical Analysis' section:

Amendments to the Safe Drinking Water Act require U.S. EPA to review each National Primary Drinking Water Regulations (NPDWR) every six years. This process, or "Six-Year Review", is a comprehensive assessment of drinking water quality that measures the state of water treatment capabilities, as well as current laboratory analytical methods for the regulated contaminants (U.S. EPA, 2010b). As described by U.S. EPA (2010d), during the Six-Year Review process, public water systems must sample homes or other sites with plumbing materials expected to contain lead or copper (i.e., homes connected to water mains by lead pipes, etc.) to detect elevated levels of chemicals (e.g., lead). In addition, drinking water samples must be first draw following a 6-hour stagnation period to allow for corrosion effects to accumulate. The findings of

---

[1] The AWWSC (1988) performed a survey of the trace element concentrations and characteristics of ███ locations throughout the United States (U.S. EPA, 1994a,b).

[2] Due to ongoing analyses of lead in drinking water, the lead dataset was not published as part of the Six-Year Review of National Primary Drinking Water Regulations (U.S. EPA, 2010a). The lead concentration in drinking water dataset obtained from the 1998-2005 National Compliance Monitoring Information Collection Request Dataset (i.e.,"Six-Year Review-ICR Dataset"), however, was delivered by U.S. EPA Office of Groundwater and Drinking Water to the TRW for this review. For more information see http://water.epa.gov/scitech/datait/databases/drink/sdwisfed/howtoaccessdata.cfm.

the sampling efforts are reported to the respective Primacy Agency (i.e., states and tribes with primary enforcement authority under the Safe Drinking Water Act) in accordance with 40 CFR 141.90 of the Lead and Copper rule, and additional actions are taken if elevated levels of lead are present (U.S. EPA, 2010d).

Data obtained from the 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a) consisted of ▮ States and Primacy Agencies that comprised of ▮▮▮ individual sample monitoring records. ~~The U.S. EPA (2009) Office of Water 6-year report data set is based on the lead concentrations obtained from the individual sample monitoring records of ▮▮▮ water suppliers³ in the United States (U.S. EPA, 2009).~~ *On average, ▮▮ water suppliers contributed data from each state; the number of suppliers varied from one in Tennessee to ▮▮▮ in Texas; on average, ▮▮ water suppliers voluntarily contributed data. The calculated geometric mean PbW was ▮▮ µg/L (▮% CI= ▮▮ to ▮▮ µg/L; see Table 3). In addition, a population-weighted mean PbW of ▮▮ µg/L (▮% CI= ▮▮ to ▮ µg/L) was calculated based on the population served by each water supplier (see Table 4).* ~~The IEUBK model uses tap water (i.e., private water and not necessarily municipal water) as the source of the water lead concentration data, and only ▮% of the reported results are from End Point sources. These are sources of uncertainty in the resulting mean. It is anticipated that this would likely result in an underestimation of lead concentration at the tap (because distribution pipes and home systems may have lead solder which could result in higher lead concentrations at the tap). On the other hand, if a residence had a water filtration system, the lead concentration at the tap would likely be lower than at the distribution site.~~ *The frequency distribution of lead concentration by reported supplier is presented in Figure 1. Estimates for lead concentration were calculated using Microsoft Access. Calculated mean population per sample: ▮▮▮ observations. The order of operations was as follows: all samples multiplied by population weight factor: value * (population / mean population), then the mean of all samples by location and finally the mean of all means by location.*

~~The reported mean lead concentration for the 6-year period was ▮▮ µg/L (▮% CI= ▮▮ to ▮▮ µg/L; see Table 2). In addition, a weighted mean was calculated based on the population served by each water supplier: ▮▮ µg/L (▮% CI= ▮▮ to ▮▮ µg/L; see Table 3). The frequency distribution of lead concentration by reported supplier is presented in Figure 1.~~

COMMENT (7): The document only explains the U.S. EPA (2009) work, based on which the new recommendation is made. It does not explain the work of Clayton et al (1999) and of U.S. EPA (2010), which are the other two sources of data that were evaluated,

---

³ ~~The monitoring records were obtained from 43 states and Tribal Nations, but did not include data from Kansas, Louisiana, Maryland, Mississippi, New Hampshire, Pennsylvania, and Washington. Tennessee provided only one result for water lead concentration data.~~

based on Table 1. What exactly are those two other datasets, how were they evaluated, and why did the TRW not select those values in the end? What are the limitations of the other two datasets, as opposed to the U.S. EPA (2009) dataset? I don't know if there is a space limit for this report, but discussion of the other two datasets is critically missing. When the document is expanded to discuss data sources in detail with careful and thoughtful documentation of limitations and strengths of each data source and document how EPA synthesized the information to justify the newly proposed water lead concentration, document organization should be kept in mind before the authors release the document to public.

COMMENT (8): Not a lot of detail is provided to compare the three new datasets that the TRW evaluated. Even for the one dataset that was eventually chosen out of the three, I was unable to find more information online on my own (see prior question and concern on the provided link), and there is not enough info provided within the report. My initial impression of Table 1 is that the other dataset of U.S. EPA (2010) is more attractive (residential samples, most recent report, consideration of log-normal distribution through geometric mean), so a lot of questions remain. Surely, the TRW has their reasons for making the choice that they did make, but those reasons are not clearly explained for me to understand.

Response to Comments 6 & 7: The Six-Year Review dataset was provided to the peer reviewers. The text was reviewed and additional technical details were added. Tables and Figure are not shown.

Text added to the 'Overview':

The current default value for the Lead Concentration in Drinking Water variable in the IEUBK model represents a national central tendency estimate for lead concentration in drinking water (PbW). ~~The TRW Lead Committee evaluated the default lead concentration in drinking water (PbW) variable of the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK model) as part of an effort to review the input variables of the model.~~ This default value ~~(Version 1.1, Build 11) is based on values~~ was derived from a combination of PbW data reported by the American Water Works Service Company, Inc. (~~U.S. EPA, 1994a~~ AWWSC, 1988) and ~~the IEUBK Model Technical Support Document (U.S. EPA, 1994b).~~ a quantitative analysis performed by Marcus (1989).[4] The TRW recommends updating the Lead Concentration in Drinking Water variable with a value derived from the U.S. EPA's Second Six-Year Review of National Primary Drinking Water Regulations, or "Six-Year Review" (U.S. EPA, 2010a,b; see Table 1).[5]

---

[4] *The AWWSC (1988) performed a survey of the trace element concentrations and characteristics of ▓▓▓▓locations throughout the United States (U.S. EPA, 1994a,b).*

[5] *Due to ongoing analyses of lead in drinking water, the lead dataset was not published as part of the Six-Year Review of National Primary Drinking Water Regulations (U.S. EPA, 2010a). The lead concentration in drinking water dataset obtained from the 1998-2005 National Compliance Monitoring Information Collection Request Dataset (i.e.,"Six-Year Review-ICR Dataset"), however, was delivered by U.S. EPA Office of Groundwater and Drinking Water to the TRW for this review. For more information see*
http://water.epa.gov/scitech/datait/databases/drink/sdwisfed/howtoaccessdata.cfm.

Text added to the 'Technical Analysis' section:

The TRW ~~Lead Committee has~~ identified ~~more recent data that provide a current and scientifically sound basis to further develop a nationally-representative value for PbW (Table 1).~~ information on PbW from seven sources (Clayton et al. 1999; Moir et al., 1996; U.S. EPA, 2006a, 2007, 2008, 2010a,c). See Table 2 for an overview of these sources. U.S. EPA (2008, 2010c) and the National Ambient Air Quality Standards (NAAQS) analysis (U.S. EPA, 2006a, 2007) suggest that a constant mean water lead concentration of 4.61 µg/L is appropriate based on data from two studies of residential water concentrations in U.S. and Canadian homes (Clayton et al., 1999, Moir et al., 1996).

~~The TRW Lead Committee evaluated water concentration data from three sources for use in the IEUBK model (Table 1; also see Attachment A). The default IEUBK model (Version 1.1, Build 11) value (■ µg/L) is based on an analysis from ■ water systems provided by the American Water Works Service Company (U.S. EPA, 1994a; as reported by Marcus, 1989). This value is intended to be a central tendency value that can be applied to sites across the United States.~~

Clayton et al. (1999) based PbW estimates on the results of the National Human Exposure Assessment Survey (NHEXAS) Phase I field studies conducted by the Research Triangle Institute and the Environmental and Occupational Health Sciences Institute. Phase I was conducted in six states in U.S. EPA Region 5 (Ohio, Michigan, Illinois, Indiana, Wisconsin, and Minnesota) between July 1995 and May 1997. The study included a series of questionnaires of personal exposure and onsite physical samples of residential water (both first-draw and flushed). Clayton et al. (1999) reported the arithmetic mean drinking water concentration for the Region 5 areas as follows: first-draw (n=■) water ■ µg/L (■% CI: ■ to ■) and flushed water (n=■) ■ µg/L (■% CI: ■ to ■) (see Table 2).

Moir et al. (1996) summarized data on PbW from ■ single-family homes serviced by municipal water drawn from a lake in Halifax, Nova Scotia, Canada. Two tap water samples over two separate occasions were collected from each location in April and June, 1987. Moir et al. (1996) noted that many of the homes sampled were serviced by lead pipe mains, and that ■% and ■% of the first-draw and flushed water samples, respectively, from the homes sampled had lead concentrations that exceeded ■ µg/L. The mean lead concentration for first-draw water was ■ µg/L (maximum=■ µg/L), and for flushed water was ■ µg/L (maximum=■ µg/L) (see Table 2).

Amendments to the Safe Drinking Water Act require U.S. EPA to review each National Primary Drinking Water Regulations (NPDWR) every six years. This process, or "Six-Year Review", is a comprehensive assessment of drinking water quality that measures the state of water treatment capabilities, as well as current laboratory analytical methods for the regulated contaminants (U.S.

EPA, 2010b). As described by U.S. EPA (2010d), during the Six-Year Review process, public water systems must sample homes or other sites with plumbing materials expected to contain lead or copper (i.e., homes connected to water mains by lead pipes, etc.) to detect elevated levels of chemicals (e.g., lead). In addition, drinking water samples must be first draw following a 6-hour stagnation period to allow for corrosion effects to accumulate. The findings of the sampling efforts are reported to the respective Primacy Agency (i.e., states and tribes with primary enforcement authority under the Safe Drinking Water Act) in accordance with 40 CFR 141.90 of the Lead and Copper rule, and additional actions are taken if elevated levels of lead are present (U.S. EPA, 2010d).

*Data obtained from the 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a) consisted of 45 States and Primacy Agencies that comprised of ▓▓▓▓ individual sample monitoring records. On average, ▓▓▓ water suppliers contributed data from each state; the number of suppliers varied from one in Tennessee to ▓▓▓ in Texas; on average, ▓▓ water suppliers voluntarily contributed data. The calculated geometric mean PbW was ▓▓ $\mu g/L$ (▓% CI= ▓▓▓ to ▓▓ $\mu g/L$; see Table 3). In addition, a population-weighted mean PbW of ▓▓ $\mu g/L$ (▓% CI= ▓▓ to ▓▓ $\mu g/L$) was calculated based on the population served by each water supplier (see Table 4). The frequency distribution of lead concentration by reported supplier is presented in Figure 1. Estimates for lead concentration were calculated using Microsoft Access. Calculated mean population per sample: ▓▓▓▓ observations. The order of operations was as follows: all samples multiplied by population weight factor: value * (population / mean population), then the mean of all samples by location and finally the mean of all means by location.*

Text added to the 'Recommendation for the IEUBK model' section:
As described in U.S. EPA (2006a, 2007, 2008, 2010a,c), the range of values (▓▓▓ to ▓ $\mu g/L$) observed in Clayton et al. (1999) and Moir et al. (1996) was considered to be representative of randomly sampled residential water in houses constructed since lead pipe and solder were banned for residential use. The mean water concentration of ▓▓ $\mu g/L$ value, however, does not address elevated background exposures encountered in homes with Pb piping and/or very corrosive water.

The Six-Year Review is considered as the "largest and most comprehensive contaminant occurrence dataset ever compiled and analyzed by EPA's Drinking Water Program" (U.S. EPA, 2010b). As such, the TRW considers this dataset as an appropriate source of information to serve as the basis for updating the IEUBK model. Based on the analysis outlined in this document, the TRW recommends updating the default Lead Concentration in Drinking Water variable in the IEUBK model using the population-weighted value derived from the 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a). This default value is considered appropriate for all applications of the IEUBK model where

current and future residential scenarios are being assessed. The TRW recommends replacing the default with site-specific information if representative site-specific information is available that meet the Data Quality Objectives of the site. The Superfund Lead-Contaminated Residential Sites Handbook has further information on collecting site-specific water lead concentration data (U.S. EPA, 2003).

COMMENT (9): Although there are likely to be differences in Superfund-impacted residences vs. general urban areas, these differences in terms of water lead concentration has not been demonstrated scientifically. Furthermore, many residences receive their water from municipal water systems, rather than local wells. That's why the reviewer could not justify the lowering the default value by ▮▮% based on this reasoning alone.

COMMENT(10): A major source of uncertainty and variability in estimating an updated drinking water Pb default value is that only a small percentage of the otherwise large water sample data set of ▮▮▮▮▮ sampled suppliers involved gathering tap-side water Pb levels rather than supply Pb levels as they left the treatment plant. As the authors recognize, treating all samples as though they were tap samples rather than treatment-only samples would provide a major underestimate of the actual Pb levels providing exposure to U.S. children.

Response to Comments 9 & 10: The Six-Year Review dataset was provided to the peer reviewers. The text was reviewed and additional technical details were added. Tables and Figure are not shown.

> **Text added to the 'Uncertainty" section:**
> *The lead and copper sampling requirements in the Six-Year Review are not designed to assess mean exposure. Rather, the sampling is intended to detect elevated levels of lead if they are occurring in a water system in order to trigger additional actions to reduce lead and copper exposure. These data likely represent the higher levels of lead found in homes served by public water systems throughout the United States. Further, EPA did not conduct quality assurance activities on the data to identify anomalies such as incorrect units, duplicate samples, etc.*

4.0 REFERENCES

American Water Works Service Company, Inc. (AWWSC). 1988. Lead at the Tap – Sources and Control: A Survey of the American Water System. pp. 1-72.

Clayton, C.A.; Pellizzari, E.D.; Whitmore, R.W.; Perritt, R.L.; and Quackenboss, J.J. 1999. National Human Exposure Assessment Survey (NHEXAS): Distributions and associations of lead, arsenic and volatile organic compounds in EPA Region 5. J. Exp. Anal. Environ. Epidemiol. 9: 381–392.

Marcus, A.H. 1989. Distribution of Lead in Tap Water. Parts I and II. Report to the U.S. Environmental Protection Agency Office of Drinking Water, Office of Toxic Substances, from Battelle Memorial Institute under Contract 68-D8-0115. January 1989.

Moir, C. M.; Freedman, B.; McCurdy, R. 1996. Metal mobilization from water-distribution systems of buildings serviced by lead-pipe mains. Can. Water Resour. J. 21: 45–52.

U.S. Environmental Protection Agency (U.S. EPA). 1994a. Guidance Manual for the Integrated Exposure Uptake Biokinetic Model for Lead in Children. Washington, D.C. EPA/540/R-93/081, PB93-963510. Available online at: http://www.epa.gov/superfund/lead/products.htm

U.S. Environmental Protection Agency (U.S. EPA). 1994b. Technical Support Document: Parameters and Equations Used in the Integrated Exposure Uptake Biokinetic Model for Lead in Children (v 0.99d). EPA 540/R-94/040, PB94-963505. Available online at: http://www.epa.gov

U.S. Environmental Protection Agency (U.S. EPA). 2003. Superfund Lead-Contaminated Residential Sites Handbook. OSWER 9285.7-50. August. Avaialble online at: www.epa.gov.

U.S. Environmental Protection Agency (U.S. EPA). 2006a. Guidance on Systematic Planning Using the Data Quality Objectives Process. EPA/240/B-06/001. Available online at: www.epa.gov

U.S. Environmental Protection Agency (U.S. EPA). 2006b. Air Quality Criteria for Lead (Final). Volume I and II. Research Triangle Park, NC: National Center for Environmental Assessment (NCEA); EPA/600/R-05/144aF-bF. October. Available online at: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=158823. Section 3.3 and Table 3-10.

U.S. Environmental Protection Agency (U.S. EPA). 2007. Lead Human Exposure and Health Risk Assessments for Selected Case Studies. Volume II: Appendices. Office of Air Quality Planning and Standards (OAQPS); EPA-452/R-07-014b Appendix H: Blood lead (PbB) prediction methods, models, and inputs. July. Available online at: http://www.epa.gov

U.S. Environmental Protection Agency (U.S. EPA). 2008. Economic Analysis for the TSCA Lead Renovation, Repair, and Painting Program Final Rule for Target Housing and Child-Occupied Facilities. Office of Pollution Prevention and Toxics. EPA Contract No. 68-W2-077. March. Available online at: http://www.nchh.org

U.S. Environmental Protection Agency (U.S. EPA). 2009a. Contaminant Occurrence Support Document for Category 1 Contaminants for the Second Six-Year Review of National Primary Drinking Water Regulations. Office of Ground Water and Drinking Water. EPA-815-B-09-010. Available online at: http://water.epa.gov

U.S. Environmental Protection Agency (U.S. EPA). 2009b. Contaminant Occurrence Support Document for Category 2 Contaminant for the Second Six-Year Review of National Primary Drinking Water Regulations. Office of Ground Water and Drinking Water. EPA-815-B-09-011. October. Available online at: http://water.epa.gov

U.S. Environmental Protection Agency (U.S. EPA). 2010a. Final Six-Year Review of National Primary Drinking Water Regulations: "Final_6Yr_Lead_12.23.10.accdb". Microsoft Access Database. As provided by Rebecca Allen, U.S. EPA Office of Groundwater and Drinking Water. Received December 23, 2010.

U.S. Environmental Protection Agency (U.S. EPA). 2010b. The Analysis of Regulated Contaminant Occurrence Data from Public Water Systems in Support of the Second Six-Year Review of National Primary Drinking Water Regulations. Office of Ground Water and Drinking Water. EPA-815-B-09-006. September. Available online at: http://water.epa.gov/scitech/datait/databases/drink/sdwisfed/howtoaccessdata.cfm

U.S. Environmental Protection Agency (U.S. EPA). 2010c. Approach for Developing Lead Dust Hazard Standards for Residences. (November 2010 Draft). Office of Pollution Prevention and Toxics (OPPT). Available online at: http://yosemite.epa.gov

U.S. Environmental Protection Agency (U.S. EPA). 2010d. Lead and Copper Rule. Monitoring and reporting guidance for public water systems. Office of Water (4606M). EPA 816-R-10-004. March 2010. Available online at: www.epa.gov/safewater

Appendix – Peer Review Comments

CHARGE QUESTIONS to REVIEWERS

for Peer Review of

**"Updating the Default Input Values for
Exposure Variables in the Integrated Exposure Uptake Biokinetic Model for
Lead in Children (IEUBK Model),** *Estimation of Lead Exposure from Water
Sources for U.S. Children: Water Lead Concentration"*

August 2013

U.S. Environmental Protection Agency (U.S. EPA). Updating the Default Input Values
for Exposure Variables in the Integrated Exposure Uptake Biokinetic Model for Lead in
Children (IEUBK Model), *Estimation of Lead Exposure from Water Sources for U.S.
Children: Water Lead Concentration.*

EPA is seeking external peer review of the scientific basis supporting the update of
several exposure variables in the Integrated Exposure Uptake Biokinetic Model for Lead
in Children (IEUBK model). The IEUBK model was developed to evaluate exposure of
children (███ months) to lead and is used to assess risk and support environmental
cleanup decisions at current or potential Superfund sites. The IEUBK model is
maintained by U.S. EPA's Technical Review Workgroup Lead Committee (TRW).

The TRW Lead Committee has identified recent data that provide a more scientifically
sound basis to develop nationally-representative, age-group specific default values for
intake rates of lead in children. Given the available data, the TRW Lead Committee
recommends updating the IEUBK model default values for the bioavailability of lead in
soil and dust, water lead concentration in the United States, as well as water
consumption, dietary consumption, and ventilation rates in children in the United
States.

The current draft recommendations include updates to the bioavailability of lead in soil
and dust, national drinking water lead concentration, as well as age-specific water, air,
and food intake values. Because site-specific information is generally preferred to
default values for exposure variables in the IEUBK model, it is anticipated that some of
these defaults may be replaced with site-specific information. The goal of this review is
to ensure that default values for exposure variables in the IEUBK model are
scientifically sound and representative of reasonably current lead exposure in the
United States.

Expertise Required:
Peer reviewers should have an advanced degree and/or extensive experience in
toxicology, risk assessment, mathematical modeling, environmental health,
environmental science, or engineering. EPA is seeking peer reviewers with expertise in

(1) water lead surveys; (2) lead toxicokinetics and toxicokinetics modeling; (3) risk assessment or exposure assessment. Familiarity with the IEUBK model is beneficial. No more than one candidate peer reviewer will be selected from the same agency, consulting firm, or university.

Peer Review Charge Questions:
As a peer reviewer, you are asked to assess the adequacy of this document to provide a clear and concise explanation of the scientific issues regarding the evaluation of and recommendation for updating the IEUBK model. Please comment on the use of the approaches and methodologies to derive default values presented in the following technical document: *Estimation of Lead Exposure from Water Sources for U.S. Children: Water Lead Concentration.* In evaluating the technical document: *Estimation of Lead Exposure from Water Sources for U.S. Children: Water Lead Concentration,* please respond to the charge questions below. If changes are to be made, please provide the technical basis for the proposed changes, citing any improvements, publications or literature that supports your response.

Section 1: General Charge Questions

1.1 QUESTION: Is the organization of the document appropriate and is the document logical, clear and concise? Has EPA clearly synthesized the scientific evidence for the updated IEUBK model input values?

> *COMMENT: Two of the reviewers agreed that the national database outlined in the Update Document was appropriate, and each reviewer agreed that the Update Document needs to be reorganized for clarity and that additional information is needed to support the methodologies used. Two of the reviewers expressed concern that the analysis was based on data that are not publicly available.*

1.2 QUESTION: Does the evidence presented support implementing the revisions to IEUBK model as default values for the U.S.?

> *COMMENT: The reviewers agreed that additional text providing the technical basis for the recommended value would be needed to support the change.*

1.3 QUESTION: What are the strengths and weaknesses of approaches and methods employed given the available data?

> *COMMENT – Strength: The reviewers agreed that the document presents more current PbW data for use in the IEUBK model.*

> *COMMENT – Weakness: The reviewers agreed that additional information is needed to address uncertainties with the data, including: clarifying that the recommended value represents water at the water distribution facility and not*

necessarily household tap water (lead solder, home water filtration systems, consumption of bottled water, etc.) and details concerning the statistics used to calculate the recommended value.

1.4 QUESTION: Given the data available, what additional technical considerations can you recommend in the derivation of default values? Is EPA using appropriate models, datasets and assumptions on which to base a scientifically credible decision?

COMMENT: The reviewers agreed that additional text providing the technical basis for the recommended value is needed to support the revisions.

1.5 QUESTION: Are you aware of any other significant data/studies that are relevant and should be included or referenced in this document? Please identify any additional studies that should be considered in the assessment of the IEUBK model values.

COMMENT: Additional studies were not identified by the peer review panel.

Section 2. Specific Charge Questions

This document recommends replacing the current IEUBK model default constant of water lead concentration (PbW) of ▉ µg/dL (based on Marcus' [1989] analysis of PbW from ▉ water systems reported by the American Water Works Service Company [U.S. EPA, 1994 a,b]) with a constant PbW of ▉ µg/L (based on U.S. EPA, 2009). This value was calculated using the mean population-weighted PbW from the U.S. EPA Office of Water six-year review data (U.S. EPA, 2009) and decreases the intake of lead by approximately ▉% across all ages.

2.1 QUESTION: Do you agree with the assessment of U.S. EPA's Office of Water Six-Year Review data (U.S. EPA, 2009)?

COMMENT: The Reviewers agreed that additional information is needed to support using the six-year review database vs. data taken directly from household tap water.

2.2 QUESTION: U.S. EPA (2010) and the National Ambient Air Quality Standards analysis (U.S. EPA, 2006, 2007) suggest that a constant PbW of ▉ µg/L is representative of water sources in the U.S. and Canada. This document recommends a PbW value of ▉ µg/L.

2.2.1 Is the rationale for the lower PbW clearly explained?

COMMENT: The Reviewers agreed that additional support is needed to clarify using the recommended values, and that the Update Document needs to be reorganized for clarity.

2.2.2 Do you support the recommendation that systematic differences in residential water lead concentrations (such as, between Superfund sites and the general urban case study) were not captured by U.S. EPA (2010)?

> *COMMENT: The Reviewers agreed that based on the amount of data and text provided, additional rationale and details concerning the evaluation of U.S. EPA (2010) are needed.*

2.3 QUESTION: Do you agree with using a population-weighted mean to account for the differences in water lead concentration for large and small water distributers? Please comment on the statistics used to derive the proposed water concentration.

> *COMMENT: The Reviewers recommended that further information be provided to describe the statistical methods used in the analysis.*

2.4 QUESTION: Do you agree that the recommendation of the new default value is an appropriate, nationally representative estimate of water lead concentration in the United States to use as the basis for a default value in the IEUBK model?

> *COMMENT: The Reviewers agreed that the Update Document needs to be reorganized for clarity and that additional information is needed to support updating the IEUBK model default values.*

2.5 QUESTION: Do you have any recommendations for additional analysis of the data?

> *COMMENT: One Reviewer suggested providing an analysis of the impacts on the IEUBK model. Another Reviewer suggested exploring additional data; and one Reviewer suggested calculating the ■^{th} UCL using ProUCL.*

2.6 QUESTION: If changes are to be made, please provide the technical basis for the proposed changes, citing any improvements, publications or literature that supports your response.

> *COMMENT: The Reviewers agreed that the Update Document needs to be reorganized for clarity and that additional information is needed to support updating the IEUBK model default values. Specifically, the reviewers noted that the document should have the following: 1) additional exploration on lead levels in tap water (vs. at lead levels at the water treatment plant); 2) detail to document the data and methods used; and 3) the impact of these changes in the IEUBK model.*

Section 3: Recommendations

Based on your reading and analysis of the information provided, please identify and submit an explanation of your overall recommendation for the updating the dietary lead intakes in the IEUBK model.

1. Acceptable as is
2. Acceptable with minor revision (as indicated)
3. Acceptable with major revision (as outlined)
4. Not acceptable (under any circumstance)

<u>COMMENTS</u>:
- *Reviewer 1: Acceptable with major revision (as outlined).*

- *Reviewer 2: Not Acceptable (under any circumstance).*
  I think the report is missing critical information. It is possible that I misunderstood some of the information, because I tried to decipher certain points since they were not explicitly provided. Also, please realize that I relied on the references you provided. To the extent that more information is readily available to you, but which is not necessarily explicitly mentioned in those references (e.g., in the cited EPA reports), I am lacking the tools to fully assess your report. If that is the case, please educate me on the points I may not have understood, by providing clearer information/references.

  I understand the challenge of making a decision without having an "ideal" dataset to rely on. Picking a single representative water lead concentration for the whole of the U.S. is not an easy task. Obviously, the U.S. EPA IEUBK model is often used as a risk assessment tool that can affect policy decisions. As such, your work is very important and I appreciate your initial effort. I don't currently have the confidence to accept the recommendation, based on the information that was provided. Should my recommendation for additional work be considered, the TRW would benefit by providing reviewers with any critical references not readily available to them (e.g., Marcus 1989 Battelle report, or EPA datasets not explicitly included in the cited EPA reports such as the dataset cited as U.S. EPA 2009).

  Based on more than 6 years of experience with lead-in-water research, my impression is that a modern default water lead level to the IEUBK model is probably a rather small number. It is even probable that if you did your analysis in a way that was better justified, you would reach a similar number as is your current recommendation of ▓ μg/L. The current dataset and analysis is not however entirely defensible. Perhaps whichever number you do select will be viewed with skepticism by certain stakeholders. However, if pros and cons are clearly documented, if the source of all data is clearly explained, and if your analysis is scientifically

justified step by step compared to other alternatives, then even the most critical reviewer would more favorably respond to it. I would be happy to further assist in your effort, and I am grateful to have had the chance to review your document entitled "Estimation of Lead Exposure from Water Sources for U.S. Children."

- *Reviewer 3: Acceptable with major revision (as outlined).*